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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,727	07/15/2003	Lene Teuber	2815-0234P	7421

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EXAMINER	
LAMBKIN, DEBORAH C	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,727	TEUBER ET AL.	
	Examiner	Art Unit	
	Deborah C Lambkin	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

DEBORAH C. LAMBKIN
PRIMARY EXAMINER

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 101

Claims 19-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. "Use" by itself is non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "treatment or alleviation" of some diseases, does not reasonably provide enablement for 1) "prevention" of all diseases associated with GABA receptor complex, and 2) "treatment or alleviation of all diseases associated with GABA receptor complex. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to list all the diseases, past, present and future, associated with GABA receptor complex such that one cannot ascertain the metes and bounds of the claimed invention. It is not seen how the mere showing of use in a GABA binding test can be extrapolated to the treatment, alleviation and/or prevention of all and any disease associated with GABA receptor complex except that some correlation is shown for this proposed nexus. Applicant has not provided any documentary evidence

to this effect. Furthermore, applicant failed to provide evidence to show that treatment, alleviation and prevention are equivalents in the pharmaceutical art.

As a result, the instant data for enablement is insufficient to support such a myriad of diseases, especially those alleged to be prevented such that it would require undue experimentation for one of ordinary skill in the art to practice the invention as claimed.

This rejection can be overcomed by deleting "prevention" and by also limiting the GABA diseases to those actually contemplated by applicant, as per claim 22.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franz et al (5,294,631).

Franz et al teach a genus of benzimidazole compounds having angiotensin II antagonistic activity wherein when the n on (CH2) is 0 and R1 is phenyl substituted CO2R4 wherein R4 is H or alkyl (see col. 4, lines 47-52), X is absent, R2 is H and R3 is (CH2)nY,Y is CO2R4 and n is 0 or 1 (see col. 4, lines 54, 59, 68; col.5, line 17), reads

on the instant genus when R' is (alk)q-R1, q is 0 or 1, R1 is CO2R2, R2 is H or alkyl, R"is (alkyl)mCO2R8,m is 0 or 1 and R8 is H alkyl.

The differences between Franz et al and the instant claims are 1) that the generic species that overlap are not specifically exemplified and 2) the exemplied species of Franz et al do not show that heteroaryl can be substituted for phenyl.

Considering the In re Baird analysis of the two genera which overlap here as described supra, there is ample motivation to substitute heteroaryl for phenyl to arrive at the exemplified species because Franz et al teach this equivalence in the art of phenyl-substituted benzimidazoles (see col.4, lines 49 and 59-68) wherein one of ordinary skill in the art would expect the resultant variants or equivalents to possess the same or similar activity. There is considerable overlap in the final activity or use albeit a different pathway, that is angiotensin II and GABA receptor complex, such as circulatory disorders.

Consequently, it would have been prima facie obvious to one having ordinary skill in the art at the time the application was filed to either choose a species from the prior art genus of Franz et al or to substitute heteroaryl for phenyl in the exemplied compounds of Franz et al to arrive at the instant overlapping and exemplified compounds, motivation being that said species or compounds would be expected to possess the same or similar properties as their known exemplified counterparts wherein further the modifications are art recognized expedients, absent some unobvious or unexpected results.

No unobvious or unexpected results are seen.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 21-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 each of U.S. Patent Nos.6,503925; 6,649,609; 6,710,044. Although the conflicting claims are not identical, they are not patentably distinct from each other because they cross embrace the same compounds when R" or R11 is heterocycle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C. Lambkin whose telephone number is 571-272-0698.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on 571-272-0699.

DEBORAH C. LAMBKIN
PRIMARY EXAMINER

Deborah C. Lambkin
Primary Patent Examiner
Art Unit 1626